PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:	Wood et al.	CONF. NO:	8540
APPLICATION NO.:	10/068,299	GROUP NO:	1651
FILING DATE:	02/06/2002	EXAMINER:	Barnhart, Lora Elizabeth
TITLE:	CELL SUSPENSION PREPARATION TECHNIQUE AND DEVICE		

Commissioner for Patents
P.O. Box 1450
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DECLARATION OF FIONA M. WOOD UNDER 37 C.F.R. § 1.132

I, Fiona M. Wood, of 5 Truro Place, City Beach, Australia 6015 hereby state:

1. I am one of the inventors of U.S. Patent Application Serial Number (U.S.S.N.) 10/068,299. I am also the Non-executive Director of Avita Medical Limited (Avita), the Assignee of record of U.S.S.N. 10/068,299.

2. I hold Bachelor of Science in Anatomy and Bachelor of Medicine and Surgery from the St. Thomas' Hospital Medical School in London. I received about ten years of training before I became a consultant plastic surgeon in 1991. I then began specializing in acute burn care and scar reconstruction. Currently I am the Winthrop Professor and Head of the Burn Injury Research Unit at the School of Surgery, the University of Western Australia. I am also the Director of the Burn Service of Western Australia and the Head of the Burns Unit at Royal Perth Hospital and Princess Margaret Hospital for Children. I am the co-founder and Chair of the McComb Foundation. In 1999 I cofounded Clinical Cell Culture (now Avita) to develop regenerative and tissue-engineered products. I have been involved in all aspects of developing the technology used in Avita products.

3. I am thoroughly familiar with the subject matter described in U.S.S.N. 10/068,299, entitled "Cell Suspension Preparation Technique and Device" by Wood, *et al.* Before signing this Declaration, I reviewed the application and portions of the file history including the Office action dated December 30, 2009.

4. I have reviewed the Office action mailed December 30, 2009. I understand that the Office action states that U.S.S.N. 10/068,299 is unpatentable over Noel-Hudson et al., *In Vitro Cell and Developmental Biology – Animal* 1993, 31:508-515 ("Noel-Hudson") and Hirobe, *Journal of Experimental Zoology* 1991, 257:184-194 ("Hirobe"). I herein provide the following statements with regard to the technical differences between U.S.S.N. 10/068,299 and Noel-Hudson and Hirobe.

5. A. We harvest cells from dermis, epidermis, and dermal-epidermal injunction of a skin[1] tissue sample. The cells are filtered to remove cellular congregates greater than 200 μM. The resulting cell suspension includes a composition of cells; this composition has a cell population comprising keratinocytes basal cells, melanocytes, and fibroblasts. The cell population of the composition and the tissue sample are comparable (i.e., similar). Furthermore, the resulting cell suspension is free of cellular congregates greater than 200 μM.

B. The Office action states that Noel-Hudson at page 509, column 1, paragraph 7 discloses a composition contains all cell types. However, Noel-Hudson at page 509, column 1, paragraph 7 discloses preparing keratinocytes according to the methods of Boyce, et al., *J. Tissue Cult. Methods* 1985, 9:83-93 ("Boyce"). Indeed, Boyce removes the epidermis from the dermis, discards the dermis, uses a Pasteur pipette to agitate the epidermal fragments, and releases keratinocytes from the epidermal pieces. Boyce at pages 85-88. At least because the epidermis is separated from the dermis before any cell suspension is prepared, and because the cell suspension prepared by gentle pipetting contains many small clumps (thus not free of cellular congregates greater than 200 μM), Noel-Hudson's composition (in view of Boyce) is different from U.S.S.N. 10/068,299. That is, at no time does Noel-Hudson produce a composition that is either identical or substantially similar to the cell suspension of U.S.S.N. 10/068,299.

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[1] The skin includes the epidermis layer and the dermis layer. The compositions of the two layers are very different; the main cell types in the epidermis layer are keratinocytes and melanocytes, whereas the dermis layer includes fibroblasts, macrophages, and mast cells. The epidermis and dermis are held together by the base membrane (or basal lamina), which forms a strong cohesive bond between them. The standard technique for separating epidermis and dermis involves heat-shock treatment or enzymatic digestion of the base membrane, and then peeling the epidermis away from the dermis. See, for example, Macdiarmid, et al., "Separation of epidermal tissue from underlying dermis and primary keratinocyte culture," *Methods Mol. Biol.* 2001, 174:401-10.

C. The Office action states that Hirobe at page 185 teaches a composition that contains all cell types. However, Hirobe at page 185 describes mechanically separating epidermal sheets from the dermis, preparing epidermal cells from the epidermal sheets, and gently and repeatedly pipetting the epidermal cells to produce a cell suspension. At least because the epidermis is separated from the dermis before any cell suspension is prepared, and because the cell suspension prepared by gentle pipetting is not free of cellular congregates greater than 200 μM, **Hirobe's composition is different from** U.S.S.N. 10/068,299. That is, at no time does Hirobe produce a composition that is either identical or substantially similar to the cell suspension of U.S.S.N. 10/068,299.

All statements made in this declaration of my knowledge are true and all statements made on information and belief are believed to be true. Moreover, these statements were made with the knowledge that willful false statements and the like made by me are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Fiona M. Wood, FRCS, FRACS, AM

Date: 28/04/10